General

Guideline Title

Apremilast for treating moderate to severe plaque psoriasis.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Apremilast for treating moderate to severe plaque psoriasis. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Nov 25. 48 p. (Technology appraisal guidance; no. 368).

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Apremilast is not recommended within its marketing authorisation for treating psoriasis, that is, for treating adults with moderate to severe chronic plaque psoriasis that has not responded to systemic therapy, or systemic therapy is contraindicated or not tolerated.

People whose treatment with apremilast was funded by the National Health Service (NHS) before this guidance was published should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Moderate to severe plaque psoriasis

Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

Clinical Specialty

Dermatology

Family Practice

Internal Medicine

Rheumatology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To assess the clinical effectiveness and cost-effectiveness of apremilast for treating moderate to severe plaque psoriasis

Target Population

Adults with moderate to severe plaque psoriasis

Interventions and Practices Considered

Apremilast

Major Outcomes Considered

- Clinical effectiveness
  - Psoriasis Area and Severity Index (PASI) response
  - Physician's Global Assessment (PGA) of disease activity
  - Time to loss of PASI-75 response
  - Complications of psoriasis (such as pruritus and nail and scalp outcomes)
  - Health-related quality of life (Dermatology Life Quality Index [DLQI] and Short-Form Health Survey [SF-36] scores)
  - Adverse effects of treatment
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this appraisal was prepared by the Centre for Reviews and Dissemination (CRD) and Centre for Health Economics (CHE) Technology Assessment Group, University of York (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of the Methods of Review(s)

The manufacturer's submission (MS) described a systematic review evaluating the clinical effectiveness and tolerability of apremilast for the treatment of moderate to severe plaque psoriasis. Four randomised controlled trials (RCTs) were identified; Psoriasis study 008 (PSOR-008) and Psoriasis study 009 (PSOR-009) both compared apremilast at the licensed dose against placebo, Psoriasis study 005 (PSOR-005; a phase 2b study) compared three different dosages of apremilast against placebo, and Psoriasis study 010 (PSOR-010; a phase 3b study) compared the licensed dose of apremilast against placebo and etanercept (50 mg once per week) against placebo. PSOR-008 and PSOR-009 were described in detail in the MS, with PSOR- 005 and PSOR-010 presented as supporting evidence.

Additional non-RCT evidence was presented; Psoriasis study 001 (PSOR-001; a pilot study), Psoriasis study 003 (PSOR-003; a phase 2 study) and Psoriasis study 004 (PSOR-004; a phase 2 study). These three trials either did not include the relevant population or did not assess apremilast at the licensed dose, so are of limited relevance.

Search Strategy

The electronic databases Medline®, Medline® In-Process, EMBASE and the Cochrane Library (including the Cochrane Database of Systematic Reviews [CDSR], the Database of Abstracts of Reviews of Effects [DARE], the Cochrane Central Register of Controlled Trials, the Cochrane Methodology Register [CMR] and the National Health Service Economic Evaluation Database [NHS EED]) were searched on 23 May 2014. The search strings used for each database were reported in the MS. The manufacturer also searched ClinicalTrials.gov for relevant clinical trials. In addition the proceedings of six conferences from January 2012 to May 2014 were hand searched using the same search criteria reported for the electronic searches; International Society for Pharmacoeconomics and Outcomes Research (ISPOR), American Academy of Dermatology (AAD), British Association of Dermatologists (BAD), European Academy of Dermatology and Venerology (EADV), European League Against Rheumatism (EULAR), American College of Rheumatology (ACR).

The methods used to identify both published and unpublished studies for the systematic review were appropriate and for the most part well reported. There were some minor details missing from the reporting of the searches; however, the manufacturer supplied further details in their response to the ERG's Points for Clarification.

All of the NICE required databases were searched together with sources for unpublished and ongoing studies. The search strategies contained in the MS were appropriate and would result in a sensitive search. The drug name, brand name, drug identification number and relevant subject headings were included in the strategies. The correct fields have been searched and the search lines have all been combined appropriately.

In the original submission it was stated that the searches were not limited by date, language or study design, which is appropriate. However, the manufacturer clarified that a limit to English language studies and human studies was applied to the searches of MEDLINE and EMBASE. This could have led to relevant foreign language papers not being identified by the search. In addition, the limit to human studies has limited the retrieval to those studies indexed as human. However there are some records in the databases that have not yet been indexed as human and therefore these could have been missed.

The search strategy for ClinicalTrials.gov provided by the manufacturer did not contain the brand name Otezla. However, after testing this, it was found that the omission of the brand name would not have resulted in any ongoing trials being missed from the search of this register.

Inclusion Criteria

Studies of any design, that assessed apremilast in patients with psoriasis, psoriatic arthritis (PsA) or any other form of psoriasis and measured any clinical or health-related quality of life (HRQL) outcomes were eligible for inclusion. Only studies reported in English were eligible for inclusion; non-English language publications, editorials, non-systematic reviews and letters were excluded.

The inclusion criteria were generally appropriate, although the systematic review searches and study selection stages of the review were undertaken to identify studies for both this appraisal and the separate appraisal of apremilast for PsA. The studies of patients with PsA were subsequently excluded from this review.

Study reports for the two main RCTs described in the MS (PSOR-008 and PSOR-009) were provided by the manufacturer rather than identified by the searches. The study report for the RCT PSOR-010 was provided by manufacturer in October 2014, after the searches had been performed, so was not included in the PRISMA flow diagram of the study selection process in the MS.

The MS states that disputes as to eligibility were referred to a third party (project lead); however, the number of reviewers undertaking each stage of study selection was not stated. Therefore, it is unclear whether appropriate methods were used to reduce the potential for reviewer bias and error. The reasons for exclusion of studies excluded at the full paper stage were not reported. The exclusion of non-English language publications increases the potential for language bias. However, despite these limitations, it is unlikely that any relevant studies of apremilast were excluded.

The PSOR-010 trial was the only trial to assess both apremilast and a biological therapy against placebo; the other three RCTs only compared apremilast with placebo. The phase 2 studies compared apremilast with a different dose of apremilast, or had no comparator.

Cost-effectiveness

ERG Comment on Manufacturer's Review of Cost-effectiveness and Supporting Evidence

Searches

The manufacturer undertook a systematic literature search to identify published evidence on the cost-effectiveness of apremilast and biologic therapies for the treatment of PsA and psoriasis. The combined search was conducted to inform both this submission and the separate submission considering apremilast for PsA (ID682). However, only the references relating to the treatment of psoriasis were subsequently considered in the manufacturer's review. The search strategies were described in the MS.

The electronic databases Medline, Medline In-Process and EMBASE were searched, and the search was conducted in Ovid. A separate search of the Cochrane Library was also undertaken. Additional searching of congress abstracts from the following meetings was carried out: ISPOR, International and European meetings, AAD, BAD, EADV, EULAR, and ACR. A supplementary search of NICE technology appraisals was also performed.

The electronic database searches were run on the 30th June 2014 and covered the period 2005 to June 2014. The additional searching of congress abstracts and NICE technology appraisals was carried out June 2014 and covered the period January 2012 to June 2014. An English language limit was applied to the searches of Medline and EMBASE.

Most of the NICE required databases were searched with the exception of EconLIT. The manufacturers clarified that the Cochrane Library was searched via the Wiley interface. However, the strategy reported in the MS does not have the correct search syntax for the Wiley interface and would not have run correctly.

The search strategies for Medline and EMBASE combine terms for psoriasis and terms for apremilast or biological therapies. The strategies incorporate correct use of text word searches, synonyms and relevant subject heading searches. All of the drug names are included in the strategies: apremilast, etanercept, adalimumab, infliximab, golimumab and ustekinumab. Searches for brand names for each drug have also been included. The correct fields have been searched, truncation has been used appropriately and the search lines have all been combined correctly.

The search strategies for the electronic databases all include a section limiting results to cost-effectiveness studies. The manufacturers clarified that this section of the strategy was a bespoke strategy, designed to limit results to cost-effectiveness studies. Although not a validated study design filter, this part of the manufacturers' strategy is fit for purpose, with a variety of search terms, both text word and subject headings, relating to cost-effectiveness methods. However, the search of the Cochrane Library, which includes NHS EED, also contains this bespoke cost-effectiveness strategy. It is unnecessary to limit searches of NHS EED to cost-effectiveness studies as this database only contains economic evaluations. Therefore, the search of NHS EED could have potentially missed relevant cost-effectiveness studies.

A limit to English language studies was applied to the searches of Medline and EMBASE; therefore, relevant foreign language papers may have been missed by the search. In addition, retrieval was limited to human studies in Medline and EMBASE; therefore; only those studies indexed as

human would have been found. However, there are some records in these databases that have not yet been indexed as human and therefore these could potentially have been missed.

Inclusion/Exclusion Criteria Used for Study Selection

The inclusion and exclusion criteria used by the manufacturer are provided in the MS. In addition to these criteria all duplicate studies were removed. The ERG considers the inclusion and exclusion criteria to be reasonable and would be expected to identify all relevant studies.

Studies Included and Excluded in the Cost-effectiveness Review

A total of 1,094 study references were identified from the electronic searches, 87 of which were duplicates and were removed, resulting in 1,007 being applied to the inclusion/exclusion criteria. A total of 940 were excluded by the application of the inclusion/exclusion criteria to their respective title/abstract. The remaining 67 studies were further considered together with 2 conference abstracts and 9 NICE technology appraisals (TAs).

Of these 78 studies, a further 42 studies were subsequently excluded based on review of the full paper.

Data from 36 publications was thus summarised and subject to data extraction. Of these 19 reported the cost-effectiveness of treatment for psoriasis as a cost per quality-adjusted life-year (QALY), and 17 reported the cost-effectiveness of treatments for PsA and as such are not relevant to this submission so also excluded from analysis.

Nine of the 19 studies considered relevant to this submission reported cost–utility analyses from a UK perspective of biological therapies for moderate-to-severe psoriasis. A further 10 studies presented cost–utility analyses of biologic therapies in countries other than the UK. None of the 19 studies considered the cost-effectiveness of apremilast for the treatment of psoriasis. No additional studies relevant to this evaluation were identified by the ERG.

Number of Source Documents

Clinical Effectiveness

- Four randomised controlled trials (RCTs) were included in the review.
- Three additional non-RCTs were also included.

Cost-effectiveness

- No published cost-effectiveness studies met the inclusion criteria.
- The manufacturer submitted an economic model.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an

independent academic centre to perform an assessment of the manufacturer's submission on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this appraisal was prepared by the Centre for Reviews and Dissemination (CRD) and Centre for Health Economics (CHE) Technology Assessment Group, University of York (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Data Extraction

The manufacturer's submission (MS) does not state how many reviewers undertook data extraction, only that data were extracted and entered directly into tables. Therefore, it is unclear whether appropriate methods were used to reduce the potential for reviewer bias and error.

Adequate data from the PSOR-008 and PSOR-009 trials were presented in the MS. The PSOR-010, PSOR-005, PSOR-004, PSOR-003 and PSOR-001 trials were presented as supporting evidence, with limited study details reported. Trials PSOR-010 and PSOR-005 both assessed apremilast at the licensed dose; therefore, further details should have been provided for these two trials that met the inclusion criteria for the review.

Quality Assessment

Quality assessment results were only presented for trials PSOR-008 and PSOR-009 in the MS. The quality of these two randomised controlled trials (RCTs) was assessed using appropriate criteria specific to RCTs; the trials were good quality. The quality assessment results were checked by the ERG.

It is unclear whether there was any quality assessment of the PSOR-010, PSOR-005, PSOR-004, PSOR-003 and PSOR-001 trials.

Evidence Synthesis

The results of trials PSOR-008 and PSOR-009 were presented separately and a pooled analysis of efficacy and safety data was undertaken. The two trials had similar patient and study characteristics; therefore, pooling their results was appropriate. However, the results were merely pooled together, rather than using statistical methods to calculate a weighted average of the trials. In view of the similarity in methods between the two studies, this is acceptable and the pooled result is likely to be reliable.

A network meta-analysis (NMA) was carried out to compare the efficacy of apremilast with adalimumab, etanercept, infliximab and two different dosages of ustekinumab (45 mg and 90 mg).

Critique of the Indirect Comparison and/or Multiple Treatment Comparison

Critique of the Methods of the NMA

The ERG used the NICE Decision Support Unit (DSU) Reviewer's Checklist to appraise the NMA; the majority of items were satisfactory and there were no major issues identified. The completed DSU Reviewer's Checklist is presented in Appendix 10.1 of the ERG report.

Bayesian NMA was conducted to pool trial results. Comparable studies identified by the systematic review were compiled to form a "network", indicating the pairwise comparisons contained within each study. NMA models were programmed in WinBUGS software using a Bayesian statistical framework. Absolute outcome estimates were calculated by estimating the weighted average (i.e., proportional to study sample size) of the outcomes observed in the placebo arm of all of the studies. The absolute estimates for the other treatments were then calculated by combining the absolute placebo estimate and the NMA-derived treatment effect. This means that the pooled overall base estimate will not be exactly the same from the result of any single trial (due to statistical aggregation), and thus the absolute estimates for the treatment comparators will also differ somewhat from the effects reported in the studies. Fixed- and random-effects models were evaluated and selection was determined by model fit statistics (i.e., deviance information criterion) to identify the best model choice. The submission included only the results for the random-effects model and so the ERG requested those for the fixed effect also. These were provided and the results were very similar.

See Section 4 of the ERG report for additional information about clinical effectiveness analysis.

Cost-effectiveness

Model Structure

In the absence of previously published cost-effectiveness analyses of apremilast for the treatment of moderate to severe plaque psoriasis, the manufacturer undertook a de novo economic evaluation using a Markov state transition cohort model. The model projects expected clinical and economic outcomes. The model is used to estimate costs, life-years gained (LYG) and quality-adjusted life-years (QALYs).

The model structure chosen is based on that developed by the University of York Assessment group in that it consists of trial and treatment (or continued use) periods. This type of model structure has been applied in previous technology appraisals (TAs) for psoriasis. However, this model structure is different from previous analyses in that it allows a comparison of treatment sequences, with up to five lines of treatment.

Figure 3 of the ERG report provides a simplified schematic of the manufacturer's sequential model used for the Psoriasis Area and Severity Index (PASI)≥10 and Dermatology Life Quality Index (DLQI)>10 population. In this base-case the apremilast treatment sequence patients are assumed to progress through four lines of treatment. These four lines of treatment are apremilast, two lines of biologic therapy (assumed to be adalimumab and etanercept in the base-case model) and best supportive care (BSC). In the comparator sequence, patients are assumed to be allowed to progress through the same two lines of biologic therapy and BSC. Patients progress through the different lines of therapy due to non-response and withdrawal.

The cycle length of the model is 28 days with a time horizon of 10 years. The cycle length was chosen to be sufficient to account for the different lengths of trial periods preceding the continued use of biologic therapies. The time horizon was selected to maintain consistency with the NICE clinical guideline 153 (CG153) analysis and as the majority of patients in both arms of the base-case are on BSC by the end of 10 years.

During each line of treatment, patients are assumed to start in a trial period and may transition to a continued use period. The trial period represents a fixed period of time (10 to 16 weeks depending on the treatment) over which the efficacy of the treatment is monitored. At the end of the trial period, if an adequate response to the treatment is reported patients move to continuous use of the treatment and stay at the PASI response level they achieved until they discontinue. If the response is inadequate patients move into the trial period of the next line of treatment or to BSC if at the end of the treatment sequence.

Table 15 of the ERG review provides a summary of the health states and their definitions. Within each treatment state in the Markov model patients can be in a number of different health states, i.e., at different PASI levels with correspondingly different health-related quality of life (HRQoL) and costs.

See Sections 5 and 6 of the ERG report for additional information on cost-effectiveness analysis.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the Appraisal Consultation Document (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the Final Appraisal Determination (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Summary of Appraisal Committee's Key Conclusions

Availability and Nature of Evidence

The company's base-case model included a treatment sequence positioning apremilast before biological therapies (adalimumab and etanercept) and best supportive care compared with a treatment sequence without apremilast. The company provided scenario analyses assessing the cost-effectiveness of apremilast positioned after biological agents (compared with a sequence with apremilast positioned before biological therapies) and apremilast as a replacement treatment for one of the biological therapies in the sequence. Given that clinical experts suggested that apremilast would extend the treatment sequence (either before or after biologicals), the Committee concluded that, although the positions and comparisons modelled by the company differed from the National Institute for Health and Care Excellence (NICE)'s original scope for this appraisal, they were generally sufficient for decision-making.

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

The Committee considered that the company's base-case results were based on uncertain assumptions about key factors driving this incremental cost-effectiveness ratio (ICER), such as monitoring costs, amount of drug waste, the likely costs associated with best supportive care and the costs associated with 'non-responders'. The Evidence Review Group (ERG) addressed these uncertainties in its exploratory analyses.

Incorporation of Health-related Quality-of-Life Benefits and Utility Values. Have Any Potential Significant and Substantial Health-related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

Following the first Committee meeting the company clarified that it had, in error, derived EuroQol-5D (EQ-5D) data from US instead of UK tariffs. The company agreed that the updated trial-based EQ-5D data were appropriate and presented revised results for the change in utility from baseline associated with the different Psoriasis Area and Severity Index (PASI) response categories in the model. The Committee noted that the company's models did not take into account the disutility values associated with adverse events, but the ERG was unable to comment on whether including these values would have affected the model results. The Committee concluded that the utility gains estimated from the company's revised model (for people with a Dermatology Life Quality Index [DLQI] score of more than 10) were plausible.

There were no additional gains in health-related quality of life (HRQoL) over those already included in the quality-adjusted life-year (QALY) calculations.

Are There Specific Groups of People for Whom the Technology Is Particularly Cost Effective?

Not applicable.

What Are the Key Drivers of Cost-effectiveness?

The ICERs were highly sensitive to the costs associated with best supportive care, and specifically whether the model included hospitalisation rates and costs from Fonia et al. (2010) or NICE's psoriasis guideline. The Committee concluded that resource use for best supportive care is closer to Fonia et al. than to estimates from NICE's guideline.

Most Likely Cost-effectiveness Estimate (Given as an ICER)

The Committee considered that the most plausible ICER available for the apremilast sequence (in which apremilast was positioned before biological therapies) was about £30,300 per QALY gained. However it noted that there was considerable uncertainty about key factors driving this ICER, such as monitoring costs, amount of drug waste, the likely costs associated with best supportive care and the costs associated with 'non-responders'.

The Committee estimated that the ICER in the less severely affected population could be twice that seen for the population with a PASI and DLQI of 10 or more, that is, about £60,000 per QALY gained for apremilast positioned before biological therapies in a population with a PASI score of 10 or more and a DLQI score of 10 or less (moderate disease), and where best supportive care was the only comparator.

The Committee concluded that a sequence in which apremilast is positioned after biological therapies would not be a cost-effective use of National Health Service (NHS) resources because it is dominated by a sequence that was not considered cost effective (apremilast positioned before biological agents).

The Committee noted that the sequences in which apremilast replaced one of the biological therapies were cost saving but less effective than the comparator sequences, resulting in ICERs that reflected 'savings per QALY lost' (ranging from £21,100 to £39,100 per QALY).

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination (FAD).

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered clinical and cost-effectiveness evidence submitted by the manufacturer of apremilast and a review of this submission by the Evidence Review Group (ERG). The main clinical effectiveness evidence came from four randomised controlled trials (RCTs). For cost-effectiveness, the Appraisal Committee considered an economic model submitted by the manufacturer.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate recommendation regarding the use of apremilast for treating moderate to severe plaque psoriasis

Potential Harms

The summary of product characteristics includes the following adverse reactions for apremilast: gastrointestinal disorders (most commonly diarrhoea and nausea), upper respiratory tract infections, headache and tension headache.

For full details of adverse reactions and contraindications, see the summary of product characteristics.

Contraindications

Contraindications

For full details of adverse reactions and contraindications, see the summary of product characteristics.

Qualifying Statements

Qualifying Statements

- This guidance represents the views of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Apremilast for treating moderate to severe plaque psoriasis. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Nov 25. 48 p. (Technology appraisal guidance; no. 368).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015 Nov 25

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Appraisal Committee

Composition of Group That Authored the Guideline

Committee Members: Dr Amanda Adler (*Chair*), Consultant Physician, Addenbrooke's Hospital; Professor Ken Stein (*Vice Chair*), Professor of Public Health, University of Exeter Medical School; Dr Ray Armstrong, Consultant Rheumatologist, Southampton General Hospital; Dr Jeff Aronson, Reader in Clinical Pharmacology, University Department of Primary Health Care, University of Oxford; Professor John Cairns, Professor of Health Economics Public Health and Policy, London School of Hygiene and Tropical Medicine; Mr Matthew Campbell-Hill, Lay member; Mr Mark Chapman, Health Economics and Market Access Manager, Medtronic UK; Professor Daniel Hochhauser, Consultant in Medical Oncology, UCL Cancer Institute; Mrs Anne Joshua, NHS 111 Pharmacy Lead, Patients and Information, NHS England; Dr Sanjay Kinra, Reader in Clinical Epidemiology and Honorary Consultant in Paediatrics, London School of Hygiene and Tropical Medicine and University College London NHS Hospitals Trust; Dr Miriam McCarthy, Consultant, Public Health, Public Health Agency, Northern Ireland; Professor Ruairidh Milne, Professorial Fellow in Public Health, Wessex Institute, University of Southampton; Dr Sanjeev Patel, Consultant Physician and Senior Lecturer in Rheumatology, St Helier University Hospital; Dr John Pounsford, Consultant Physician, Frenchay Hospital, Bristol; Dr Danielle Preedy, Lay Member; Ms Marta Soares, Research Fellow, Centre for Health Economics, University of York; Dr Nicky Welton, Senior Lecturer in Biostatistics/Health Technology Assessment, University of Bristol; Dr Nerys Woolacott, Senior Research Fellow, Centre for Health Economics, University of York

Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the National Institute for Health and Clinical Excellence (NICE) Web site . Also available for download in ePub or eBook formats from the NICE Web site .

Availability of Companion Documents

The following are available:

- Wade R, Hinde S, Yang H, Harden M, Palmer S, Woolacott N, Spackman E. Apremilast for treating moderate to severe plaque psoriasis: a single technology appraisal. York (UK): Centre for Reviews and Dissemination (CRD) and Centre for Health Economics (CHE) Technology Assessment Group, University of York; 2015. 152 p. Available from the National Institute for Health and Clinical Excellence (NICE) Web site .
- Apremilast (Otezla®) for the treatment of moderate to severe plaque psoriasis. Manufacturer's submission. Uxbridge (UK): Celgene UK; 2015 Jan. 305 p. Available from the NICE Web site .

Patient Resources

The following is available:

- Apremilast for treating moderate to severe plaque psoriasis. Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2015 Nov 25. 2 p. (Technology appraisal guidance; no. 368). Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download in ePub and eBook formats from the NICE Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on February 24, 2016.

The National Institute for Health and Care Excellence (NICE) has granted the National Guideline Clearinghouse (NGC) permission to include summaries of their Technology Appraisal guidance with the intention of disseminating and facilitating the implementation of that guidance. NICE has not verified this content to confirm that it accurately reflects the original NICE guidance and therefore no guarantees are given by NICE in this regard. All NICE technology appraisal guidance is prepared in relation to the National Health Service in England and Wales. NICE has not been involved in the development or adaptation of NICE guidance for use in any other country. The full versions of all NICE guidance can be found at

www.nice.org.uk.

Copyright Statement

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ„¢ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion-criteria.aspx.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.